SUMMARY OF PRODUCT CHARACTERISTIC

CAPD/DPCA 17 STAY SAFE LINK

SOLUTION FOR PERITONEAL DIALYSIS

PRODUCT DESCRIPTION

Solution for peritoneal dialysis
Clear colorless to slightly yellow solution
Theoretical osmolarity 356 mOsm/l
pH ≈ 5.5

Composition
1 liter of solution contains:

Glucose monohydrate (equivalent to 15.0 g glucose)	16.5 g
Sodium chloride	5.786 g
Sodium lactate	3.925 g
Calcium chloride dihydrate	0.1838 g
Magnesium chloride hexahydrate	0.1017 g

PHARMACODYNAMIC

Pharmacotherapeutic group: Peritoneal dialytic, hypertonic solutions
ATC code: B05D B
CAPD/DPCA 17 Stay Safe Link Solution for Peritoneal Dialysis, also known as CAPD 17, represents lactate-buffered, glucose-containing electrolyte solution intended for intraperitoneal administration for the treatment of end-stage renal failure of any origin by continuous ambulatory peritoneal dialysis (CAPD). The calcium dialysis concentration of this peritoneal dialysis solution is set at 1.25 mmol/l which has been shown to reduce the risk of hypercalcaemia during the concomitant treatment with calcium-containing phosphate binders and/or vitamin D.

The characteristic of continuous ambulatory peritoneal dialysis (CAPD) is more or less continuous presence of usually 2 liters of dialysis solution in the peritoneal cavity which is replaced by fresh solution three to five times a day.

The basic principle behind every peritoneal dialysis technique is the use of peritoneum as a semi-permeable membrane allowing the exchange of solutes and water between the blood and the dialysis solution by diffusion and convection according to their physico-chemical properties.
The electrolyte profile of the solution is basically the same as that of physiological serum, although it has been adapted (e.g. the potassium content) for use in uraemic patients to enable renal function substitution therapy by means of intraperitoneal substance and fluid exchange. Substances which are normally eliminated with the urine, such as urea, creatinine, inorganic phosphate, uric acid, other solutes and water, are removed from the body into the dialysis solution. It should be borne in mind that medication may also be eliminated during dialysis, and that a dose adjustment may thus be necessary.

Individual parameters (such as patient size, body weight, laboratory parameters, residual renal function, ultrafiltration) must be used to determine the dose and combination of solutions required with differing osmolarity (glucose content), potassium, sodium, and calcium concentrations. The efficacy of therapy should be regularly monitored on the basis of these parameters.

Peritoneal dialysis solutions with a high glucose concentration (2.3 % or 4.25 %) are used when the body weight is above the desired dry weight. The withdrawal of fluid from the body increases in relation to the glucose concentration of the peritoneal dialysis solution.

PHARMACOKINETIC
Uraemic retention products such as urea, creatinine, and uric acid, inorganic phosphate, and electrolytes such as sodium, potassium, calcium and magnesium are removed from the body into the dialysis solution by diffusion and/or convection.

Dialysate glucose is used as an osmotic agent in CAPD 17 is slowly absorbed decreasing the diffusion gradient between dialysis solution and extracellular fluid. Ultrafiltration is maximal at the beginning of the dwell time reaching a peak after about 2 to 3 hours. Later absorption starts with a progressive loss of ultrafiltrate. After 4 hours the ultrafiltrate averages 100 ml with a 1.5 %, 400 ml with a 2.3 %, and 800 ml with a 4.25 % glucose solution. 60 to 80 % of dialysate glucose is absorbed.
S-Lactate used as the buffering agent is almost completely absorbed after a 6-hour dwell time. In patients with a normal hepatic function, S-lactate is rapidly metabolized demonstrated by normal values of intermediate metabolites.

Calcium mass transfer depends on the dialysis solution of glucose concentration, the effluent volume, the serum ionized calcium, and the calcium concentration in the dialysis solution. The higher the glucose concentration, the effluent volume and the serum ionized calcium concentration, and the lower the calcium concentration in the dialysis solution, the higher is the calcium transfer from the patient to the dialysate. It has been estimated that a typical CAPD schedule of three 1.5% and one 4.25% glucose-containing bags per day would remove up to 160 mg calcium per day enabling a higher intake of oral calcium containing drugs and vitamin D without the risk of hypercalcaemia.

INDICATIONS
End-stage (decompensated) chronic renal failure of any origin which can be treated with peritoneal dialysis.

RECOMMENDED DOSE
Posology
CAPD 17 is exclusively indicated for intraperitoneal use.
The mode of therapy, frequency of administration, and dwell time required will be specified by the attending physician.

Adults:
Unless otherwise prescribed, patients will receive an infusion of 2,000 ml solution per exchange four times a day. After a dwell time between 2 and 10 hours, the solution will be drained.
Adjustment of dosage, volume and number of exchanges will be necessary for individual patients.

If dilation pain occurs at the commencement of peritoneal dialysis treatment, the solution volume per exchange should be temporarily reduced to 500-1500ml.

In large patients and if residual renal function is lost, an increased volume of dialysis solution will be necessary. In these patients, or patients who tolerate larger volumes, a dose of 2500 – 3000 ml solution per exchange may be given.

Pediatric population:
In children the solution volume per exchange should be prescribed according to age and body surface area (BSA).

For initial prescription, the volume per exchange should be 600 – 800 ml/m2 BSA with 4 (sometimes 3 or 5) exchanges per day. It can be increased up to 1000 ml/m2 BSA depending on tolerance, age and residual renal function.

There are no special dosage recommendations for elderly patients.
Peritoneal dialysis is a long term therapy involving repeated administrations of single solutions.

ROUTE OF ADMINISTRATION
Method and duration of administration
Patients must be trained appropriately, must practice the technique and be shown to be proficient at performing peritoneal dialysis before performing it at home. The training should be performed by qualified personnel. The attending physician must ensure that the patient masters the handling techniques sufficiently before the patient performs peritoneal dialysis at home. In case of any problems or uncertainty the attending physician should be contacted.
Dialysis using the prescribed doses should be performed daily and should be continued for as long as renal function substitution therapy is required.

Continuous ambulatory peritoneal dialysis (CAPD):
The solution is first warmed to body temperature. For bags with a volume up to 3,000 ml this should be done using an appropriate heater tray. The heating time for a 2,000 ml bag with a starting temperature of 22°C is approx. 120 min. The temperature control is done automatically and is set to 39°C ±1°C. More detailed information can be obtained from the operating instructions of the bag warmer. Use of microwaves is not recommended due the risk of local overheating.

The appropriate dose is infused in the peritoneal cavity using a peritoneal catheter over 5 - 20 minutes. Depending on physician's instructions, the dose should dwell in the peritoneal cavity for 2 - 10 hours (equilibrium time), and then be drained.

Depending on the required osmotic pressure, CAPD 17 can be used sequentially with other peritoneal dialysis solutions with higher glucose content (i.e. with higher osmolarity).

CONTRA-INDICATIONS
For this specific peritoneal dialysis solution
CAPD 17 must not be used in patients with lactic acidosis, severe hypokalaemia, and severe hypocalcaemia.
Due to the content of fructose, this medicinal product is not suitable for patients with fructose intolerance (hereditary fructose intolerance). A non-recognised hereditary fructose intolerance must be excluded prior to administration to babies and infants.

For peritoneal dialysis treatment in general
A peritoneal dialysis treatment should not be commenced in case of:
- recent abdominal surgery or injury, a history of abdominal operations with fibrous adhesions, severe abdominal burns, bowel perforation
- extensive inflammatory conditions of the abdominal skin (dermatitis),
- inflammatory bowel diseases (Crohn's disease, ulcerative colitis, diverticulitis),
- peritonitis,
- internal or external abdominal fistula,

- umbilical, inguinal or other abdominal hernia,
- intra-abdominal tumours,
- ileus,
- pulmonary disease (especially pneumonia),
- sepsis,
- extreme hyperlipidaemia,
- in rare cases of uraemia, which cannot be managed by peritoneal dialysis,
- cachexia and severe weight loss, particularly in cases in which the ingestion of adequate protein is not guaranteed,
- patients who are physically or mentally incapable of performing peritoneal dialysis as instructed by the physician.

If any of the above mentioned disorders develops during the peritoneal dialysis treatment, the attending physician has to decide on how to proceed.

WARNING AND PRECAUTION

The solution for peritoneal dialysis must not be used for intravenous infusion.
CAPD 17 should only be administered after careful benefit-risk assessment in:

- loss of electrolytes due to vomiting and/or diarrhoea (a temporary change to a peritoneal dialysis solution containing potassium might then become necessary).
- hyperparathyroidism: The therapy should comprise the administration of calcium-containing phosphate binders and/or vitamin D to ensure adequate enteral calcium supply.
- hypocalcaemia: It may be necessary to use peritoneal dialysis solutions with a higher calcium concentration either temporarily or permanently in case an adequate enteral supply with calcium by calcium-containing phosphate binders and/or vitamin D is not possible.
- patients receiving digitalis therapy: Regular monitoring of the serum potassium level is mandatory. Severe hypokalaemia may necessitate the use of a potassium-containing dialysis solution together with dietary counselling.

Peritoneal dialysis solutions with a high glucose concentration (2.3 % or 4.25 %) should be used cautiously to protect the peritoneal membrane with care, to prevent dehydration and to reduce the glucose load.

A loss of proteins, amino acids, and water-soluble vitamins occurs during peritoneal dialysis. To avoid deficiencies an adequate diet or supplementation should be ensured.
The transport characteristics of the peritoneal membrane may change during long-term peritoneal dialysis primarily indicated by a loss of ultrafiltration. In severe cases peritoneal dialysis must be stopped and haemodialysis commenced.

<u>Regular monitoring of the following parameters is recommended:</u>

- body weight for the early recognition of over-hydration and dehydration,
- serum sodium, potassium, calcium, magnesium, phosphate, acid base balance and blood proteins,
- serum creatinine and urea,
- blood sugar,
- parathormone and other indicators of bone metabolism,
- residual renal function in order to adapt the peritoneal dialysis treatment.

CAPD 17 contains 15 g glucose in 1000 ml solution. This should be taken into account in patients with diabetes mellitus.
The effluent should be checked for clarity and volume. Turbidity and/ or abdominal pain are indicators of peritonitis.

Elderly patients

The increased incidence of hernia should be considered in elderly patients prior to the start of peritoneal dialysis.

Addition of medication to the peritoneal dialysis solution:

The addition of medication to the peritoneal dialysis solution is generally not recommended because of the risk of contamination and of incompatibility between the peritoneal dialysis solution and the medication.

When adding drugs, use aseptic technique, mix thoroughly and after checking for the absence of any turbidity, which may occur due to incompatibilities, the peritoneal dialysis solution must be used immediately.

Handling:

Plastic containers may occasionally be damaged during transport or storage. This can result in a contamination with growth of microorganisms in the dialysis solution. Thus all containers should be carefully inspected for damage prior to connection of the bag and prior to use of the peritoneal dialysis solution. Any damage, even minor, to connectors, at the closure, container welds and corners, must be noted because of possible contamination.

Damaged bags or bags with cloudy content should never be used! In case of doubt the attending physician should decide on the use of the solution.

Only use the peritoneal dialysis solution if container and seal are undamaged.

The overwrap should only be removed before administration.

Aseptic conditions must be maintained during dialysate exchange in order to reduce the risk of infection.

SPECIAL PRECAUTIONS FOR DISPOSAL

1. Check the solution bag (label, the expiry date and ensure that the solution is clear) – open the overwrap and the packaging of the disinfection cap.
2. Clean hands with an antimicrobial washing solution.
3. Place the DISC into the organizer (suspend solution bag from the upper hole of the infusion pole – unroll the line “solution bag-DISC” – place the DISC into the organizer – afterwards place drainage bag into lower holder of the infusion pole).
4. Place catheter extension into one of the two inserts of the organizer. Place the new disinfection cap into the other free insert.
5. Disinfect your hands and remove protection cap of the DISC.
6. Connect catheter extension to the DISC.
7. Open clamp on extension – position “●“ – outflow procedure starts.
8. After completion of the outflow: Flush-position “●●“ -flush of fresh dialysate to the drainage bag (approx. 5 seconds).
9. Inflow – position “○◑●“ – connection between solution bag and catheter.
10. Security step – position “●●●●“ – automated closing of the catheter extension with the PIN.
11. Disconnection - remove the protection cap from the new disinfection cap and screw it onto the old one. Unscrew catheter extension from the DISC and screw onto the new disinfection cap.
12. Close the DISC with the open end of the protection cap (which has remained in the right hole of the organizer)
13. Check the drained dialysate for clarity and weight and, if the effluent is clear, discard it.

DRUG INTERACTION

The use of this peritoneal dialysis solution can yield to a loss of efficacy of other medication if these are dialysable through the peritoneal membrane. A dose adjustment might become necessary.

A distinct reduction of the serum potassium level can increase the frequency of digitalis-associated adverse reactions. Potassium levels must be monitored particularly closely during concurrent digitalis therapy.

Special attention and monitoring is required in the case of hyperparathyroidism. Therapy should include the administration of calcium-containing phosphate binders and/or vitamin D to ensure adequate enteral calcium supply.
Use of diuretic agents may help maintain residual renal function, but may also result in water and electrolyte imbalances.

In diabetic patients the daily dose of insulin or oral hypoglycaemic medicinal products must be adjusted to take account of the increased glucose load.

PREGNANCY & LACTATION

Pregnancy

There are no data from the use of CAPD 17 in pregnant women. No animal reproductive toxicity studies have been performed. No pre-clinical toxicity studies with CAPD 17 have been carried out, but clinical studies with comparable solutions for peritoneal dialysis have shown no major risk of toxicity. CAPD 17 should not be used during pregnancy unless the clinical condition of the woman requires treatment with CAPD 17.

Breast-feeding

It is unknown whether CAPD 17 active substances/metabolites are excreted in human milk. Breast-feeding is not recommended for mothers on peritoneal dialysis.

SIDE EFFECTS

Possible adverse reactions may result either from the peritoneal dialysis treatment itself or may be induced by the dialysis solution.
The adverse drug reactions are ranked under the headings of reporting frequency using the following convention:

very common	≥ 1/10
Common	≥ 1/100 to <1/10
Uncommon	≥ 1/1,000 to <1/100
Rare	≥ 1/10,000 to <1/1,000
very rare	<1/10,000
not known	Cannot be estimated from the available data

Potential adverse reactions of the peritoneal dialysis solution

Endocrine disorders

- Secondary hyperparathyroidism with potential disturbances of the bone metabolism (not known)

Metabolism and nutrition disorders

- Increased blood sugar levels (common)

- Increase in body weight due to the continuous uptake of glucose form the peritoneal dialysis solution (common)
- Hyperlipidaemia or deterioration of pre-existing hyperlipidaemia (common)

Cardiac and vascular disorders
- Hypotension (uncommon)
- Tachycardia (uncommon)
- Hypertension (uncommon)

Respiratory, thoracic and mediastinal disorders
- Dyspnoea (uncommon)

Renal and urinary disorders
- Electrolyte disturbances, e.g. hypokalaemia (very common)
- Hypocalcaemia (uncommon)

General disorders and administration site conditions
- Dizziness (uncommon)
- Oedema (uncommon)
- Disturbances in fluid balance (uncommon) indicated either by a rapid decrease (dehydration) or increase (overhydration) in body weight. Severe dehydration might occur when using solutions of higher glucose concentration.

<u>Potential adverse reactions of the treatment mode</u>
Infections and infestations
- Peritonitis (very common) peritonitis indicated by a cloudy effluent. Later abdominal pain, fever, and general malaise may develop or, in very rare cases, sepsis. The patient should seek medical advice immediately.
  The bag with the cloudy effluent should be closed with a sterile cap and assessed for microbiological contamination and white blood cell count.
- Skin exit site and tunnel infections (very common) indicated by redness, oedema, exudations, crusts and pain at the catheter exit site.
  In case of skin exit site and tunnel infections the attending physician should be consulted as soon as possible.

Respiratory, thoracic and mediastinal disorders
- Dyspnoea caused by the elevated diaphragm (not known)

Gastrointestinal disorders
- Hernia (very common)
- Abdominal distension and sensation of fullness (common)
- Diarrhoea (uncommon)
- Constipation (uncommon)

Injury, poisoning and procedural complications
- In- and outflow disturbances of the dialysis solution (common)
- Shoulder pain (common)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

SYMPTOMS & TREATMENT OF OVERDOSAGE

No emergency situations in connection with overdose have been reported.
Any excess of dialysis solution infused in the peritoneal cavity can easily be drained into the drainage bag. In case of too frequent bag exchanges, dehydration and/or electrolyte disturbances can result which necessitate immediate medical attention. If an exchange has been forgotten, then the attending physician or dialysis centre in charge should be contacted.
Incorrect balancing can lead to hyper- or dehydration and electrolyte disturbances.
The most likely consequence of an overdosage with CAPD 17 is dehydration.
Underdosage, interruption of treatment or discontinuation of treatment may lead to life-threatening hyperhydration with peripheral oedema and cardiac decompensation and/or other symptoms of uraemia, which may endanger life.
The generally accepted rules for emergency care and intensive therapy must be applied. The patient may require immediate haemodialysis.

STORAGE CONDITION

Store below 30°C.
Do not refrigerate or freeze.
Keep out of reach and sight of children

SHELF-LIFE

2 years

ATC THERAPEUTIC CODE

ATC code: B05D B

PRESENTATION

CAPD/DPCA 17 Stay Safe Link solution for peritoneal dialysis
Box, 6 plastic bags @ 2 bags (2 L CAPD/DPCA solution bag + drainage bag)
Reg. No. .....

Manufactured by:
Fresenius Medical Care Production Sdn. Bhd.
Lot 34618, PT 29466, Techpark @ Enstek
71760 Bandar Enstek, Negeri Sembilan, Malaysia

Imported and Distributed by:
PT Fresenius Medical Care Indonesia, Jakarta, Indonesia

Product License Holder:
PT Ethica Industri Farmasi, Indonesia

ON MEDICAL PRESCRIPTION ONLY
HARUS DENGAN RESEP DOKTER

DISETUJUI OLEH BPOM : 22/09/2020 ID: EREG100407VR12000045

FRESENIUS MEDICAL CARE

CAPD/DPCA 17
stay•safe link
Calcium chloride dihydrate, Sodium chloride, Sodium lactate, Magnesium chloride hexahydrate, Glucose monohydrate
Solution for Peritoneal Dialysis

Indonesia Leaflet: Informasi untuk pengguna CAPD/DPCA 17 Larutan untuk Peritoneal Dialisis

Baca semua isi dari leaflet ini dengan baik sebelum Anda mulai menggunakan CAPD/DPCA 17, karena leaflet ini mengandung informasi yang penting untuk Anda.

- Simpan leaflet ini. Anda mungkin membutuhkannya untuk dibaca kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan pada dokter, farmasis atau perawat Anda.
- Obat ini telah diresepkan khusus hanya untuk Anda. Jangan meneruskan obat ini kepada orang lain, hal tersebut dapat melukai mereka, bahkan sekalipun jika gejala-gejala dan sakit yang dialami sama dengan Anda.
- Jika Anda mengalami efek samping yang menjadi semakin serius, komunikasikan dengan dokter , farmasis atau perawat Anda. Hal ini termasuk efek samping yang mungkin tidak ada di leaflet ini. Lihat bagian 4.

Apa yang ada di leaflet ini

1. Apa itu CAPD/DPCA 17 dan apa kegunaannya
2. Apa yang perlu Anda ketahui sebelum menggunakan CAPD/DPCA 17
3. Bagaimana cara menggunakan CAPD/DPCA 17
4. Efek samping yang mungkin terjadi
5. Bagaimana cara penyimpanan CAPD/DPCA 17
6. Isi dari kemasan dan informasi lain

1. Apa itu CAPD/DPCA 17 dan apa kegunaannya

CAPD/DPCA 17 digunakan untuk membersihkan darah melalui peritoneum pada pasien dengan stadium akhir gagal ginjal kronis. Tipe cuci darah seperti ini disebut sebagai peritoneal dialisis.

2. Apa yang perlu Anda ketahui sebelum menggunakan CAPD/DPCA 17

Jangan gunakan CAPD/DPCA 17 apabila:

- Kadar kalium di dalam darah Anda terlalu rendah
- Kadar kalsium di dalam darah Anda terlalu rendah
- Anda menderita gangguan metabolisme asam laktat
- Anda menderita gangguan metabolisme fruktosa (secara genetic menderita intoleransi fruktosa).

Terapi peritoneal dialisis tidak boleh dimulai apabila Anda memiliki:

- Gangguan di daerah abdominal seperti:
  - Luka, atau setelah operasi.
  - Luka bakar berat
  - Reaksi peradangan kulit yang luas
  - Peradangan peritoneum
  - Luka yang baru mulai dan belum sembuh
  - Hernia umbilical, inguinal atau diafragmatik
  - Tumor di daerah abdominal atau lambung
- *Inflammatory Bowel Diseases*
- Obstruksi intestinal
- Penyakit paru-paru, khususnya pneumonia
- Keracunan darah yang disebabkan oleh bakteri
- Kadar lemak di dalam darah yang ekstrim tinggi
- Keracunan karena adanya urin di dalam darah yang tidak dapat diterapi dengan membersihkan darah
- Malnutrisi dan kehilangan berat badan yang berat, khususnya jika intake makanan yang mengandung protein secara cukup tidak memungkinkan

Peringatan dan Perhatian

Informasikan kepada dokter Anda segera apabila:

- Anda mengalami kehilangan elektrolit (garam) yang berat karena muntah dan/atau diare
- Anda mengalami paratiroid yang overaktif atau kadar kalsium yang rendah di dalam darah, mungkin diperlukan konsumsi zat tambahan seperti pengikat fosfat dan/atau vitamin D. Jika konsumsi zat tambahan tidak memungkinkan, diperlukan penggunaan larutan peritoneal dialisis dengan kadar kalsium tinggi.
- Anda mengalami peradangan peritoneum, dapat dilihat dengan keruhnya cairan dialisat, nyeri abdominal, demam, merasa tidak enak badan atau pada beberapa kasus yang jarang adalah keracunan darah. Silahkan tunjukkan kantong yang mengandung cairan dialisat tersebut kepada dokter Anda.

Peritoneal dialisis dapat menyebabkan kehilangan protein dan vitamin larut air. Diet dengan suplemen nutrisi direkomendasikan untuk menghindari status defisiensi.

Dokter Anda akan mengevaluasi keseimbangan elektrolit (garam), jumlah sel-sel darah, fungsi ginjal, berat badan dan status nutrisi Anda.

CAPD/DPCA 17 mengandung 15 gram glukosa dalam larutan 1000 mL. Hal ini harus menjadi pertimbangan khusus pada pasien dengan Diabetes Mellitus.

Obat-obat lain dan CAPD/DPCA 17

Informasikan kepada dokter atau farmasis Anda jika Anda mengkonsumsi, baru saja mengkonsumsi obat-obat lain.

Hal ini diperlukan karena peritoneal dialisis dapat mempengaruhi efek obat-obat tersebut, dokter Anda mungkin perlu melakukan perubahan dosis, khususnya untuk obat-obat sebagai berikut:

- Obat-obat untuk gagal jantung, seperti digitoksin. Dokter Anda akan mengevaluasi kadar kalium di dalam darah Anda dan, jika diperlukan, akan melakukan pengukuran yang sesuai.
- Obat-obat yang mempengaruhi kadar kalsium, seperti obat-obat yang mengandung kalsium atau vitamin D.
- Obat-obat yang meningkatkan ekskresi urin seperti diuretic.
- Obat-obat yang dikonsumsi secara oral yang dapat menurunkan kadar glukosa di dalam darah atau insulin. Kadar glukosa darah Anda harus selalu dipantau secara rutin.

Kehamilan dan Menyusui

Jika Anda hamil atau menyusui, berpikir Anda hamil, atau merencanakan untuk memiliki bayi, tanyakan/ mintalah saran kepada dokter Anda sebelum Anda memutuskan menggunakan CAPD/PDCA 17 ini.

Tidak ada data yang cukup mengenai penggunaan CAPD/DPCA 17 pada wanita hamil dan/atau pada masa menyusui.

Jika Anda hamil, Anda seharusnya tidak menggunakan CAPD/PDCA 17, kecuali dokter Anda mempertimbangkan bahwa hal ini memang diperlukan secara mutlak.

Tidak diketahui apakah substansi/metabolit dari CAPD/DPCA 17 diekskresikan melalui air susu Ibu. Pada Ibu yang menggunakan CAPD/DPCA 17 untuk peritoneal dialisis tidak direkomendasikan untuk menyusui.

Mengemudi dan menggunakan mesin

JIka CAPD/DPCA 17 digunakan sesuai dengan dosis yang diresepkan oleh dokter, tidak ada gangguan pada kemampuan untuk mengemudi dan/atau menggunakan mesin.

3. Bagaimana cara menggunakan CAPD/DPCA 17

Selalu gunakan obat ini sesuai dengan yang dokter atau farmasis Anda katakan. Jika Anda tidak yakin, komunikasikan kembali dengan dokter atau farmasis Anda.

Dokter Anda akan menjelaskan mengenai metode, lama dan frekuensi penggunaan dan volume larutan / cairan yang dibutuhkan, serta waktu yang dibutuhkan untuk larutan / cairan tersebut tetap berada di rongga peritoneum.

Jika ada tekanan di daerah abdominal Anda, dokter Anda mungkin akan mengurangi volume larutan / cairan yang digunakan.

CAPD (*Continuous Ambulatory Peritoneal Dialysis*):

- Dewasa: dosis umum adalah 2000 – 3000 mL, 4x sehari, tergantung dari berat badan dan fungsi ginjal. Setelah 2 – 10 jam di dalam rongga peritoneum, larutan / cairan dikeringkan.
- Anak-anak: dokter akan menentukan volume larutan / cairan dialisis yang dibutuhkan, tegantung dari toleransi, usia dan luas area permukaan tubuh (BSA) anak.

  Rekomendasi dosis inisial adalah 600 – 800 mL/m^2 (sampai dengan 1000 mL/m^2 sepanjang malam) BSA 4x sehari.

Gunakan CAPD/DPCA 17 hanya pada rongga peritoneum.

Gunakan CAPD/DPCA 17 hanya jika larutan / cairan jernih dan kantong tidak mengalami kerusakan.

DISETUJUI OLEH BPOM: 22/09/2020 ID: EREG100407VR12000045

Instruksi penanganan

Sistem stay safe link untuk CAPD:

Kantong larutan / cairan dihangatkan sesuai dengan suhu tubuh. Hal ini harus dilakukan dengan menggunakan penghangat yang sesuai.

Waktu untuk menghangatkan kantong berisi 2000 mL dengan suhu awal 22˚C adalah sekitar 120 menit.

Informasi lebih detil dapat dilihat pada bagian instruksi operasional dari penghangat kantong.

Tidak boleh menggunakan microwave, karena akan ada risiko *overheating* (terlalu panas).

Setelah larutan / cairan dihangatkan, Anda dapat mulai melakukan pertukaran kantong.

1. Cek kantong larutan / cairan (penandaan, tanggal kadaluarsa, kejernihan larutan / cairan, kantong dan penutup luar tidak ada kerusakan) ▸ buka penutup kantong dan bagian "*disinfection cap*".
2. Bersihkan tangan Anda dengan larutan pencuci yang mengandung antimikrobial / antibakterial.
3. Tempatkan DISC ke dalam organizer (gantung kantong larutan / cairan di tiang infus pada lubang bagian atas ▸ buka gulungan line DISC kantong larutan / cairan ▸ tempatkan DISC pada organizer ▸ tempatkan kantong pengeringan di tiang infus pada lubang bagian bawah)
4. Tempatkan ekstensi kateter pada DISC
5. Disinfeksi tangan Anda dan lepaskan tutup perlindungan dari DISC.
6. Hubungkan ekstensi kateter pada DISC
7. Buka penjepit ekstensi ▸ posisi ● ▸ prosedur *outflow* dimulai.
8. Bilas ▸ posisi ●● ▸ bilas dialisat yang baru ke dalam kantong pengeringan (sekitar 5 detik)
9. *Inflow* ▸ posisi "○◑●" ▸ hubungkan kantong larutan / cairan dengan kateter.
10. Langkah keamanan ▸ posisi ●●●● ▸ tutup ekstensi kateter dengan memposisikan di PIN.
11. Diskoneksi (lepaskan ekstensi kateter dari DISC) ▸ putar tutup disinfektan yang baru pada ekstensi kateter.
12. Tutup DISC. Tutup DISC dengan bagian terbuka dari tutup pengaman dengan menggunakan tutup disinfektan (tempatkan tepat di lubang dari *organizer*).
13. Cek dialisat yang dikeringkan dan buang.

Setiap kantong hanya boleh digunakan sekali dan larutan / cairan yang tersisa tidak boleh digunakan lagi.

Setelah training yang sesuai, CAPD/DPCA 17 dapat digunakan secara mandiri di rumah. Pastikan bahwa Anda mengikuti seluruh prosedur yang Anda pelajari selama training dan selalu jaga kondisi higienis ketika melakukan penggantian kantong.

Selalu cek dialisat yang dikeringkan, dalam hal kekeruhan.

Lihat bagian 2 "Peringatan dan Perhatian dengan CAPD/DPCA 17.

Jika Anda menggunakan CAPD/PDCA 17 melebihi yang seharusnya.

Jika Anda mengalirkan terlalu banyak larutan / cairan ke dalam rongga peritoneum, kelebihannya dapat dikeringkan / dikeluarkan.

Jika Anda menggunakan terlalu banyak kantong pada saat peritoneal dialisis, segera hubungi dokter Anda, karena kemungkinan terjadinya ketidakseimbangan cairan dan/atau elektrolit

Jika Anda lupa menggunakan CAPD/DPCA 17

Untuk menghindari risiko kemungkinan konsekuensi membahayakan nyawa (life treathening), Anda harus menghubungi dokter Anda.

Jika Anda mempunyai pertanyaan lebih lanjut mengenai penggunaan produk ini, tanyakan kepada dokter atau farmasis Anda.

Jika Anda berhenti menggunakan CAPD/ DPCA

Jika Anda menghentikan pembersihan darah tanpa memulai pengobatan alternatif, bisa ada konsekuensi yang mengancam jiwa. Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan produk ini, tanyakan kepada dokter atau apoteker Anda.

4. Efek samping yang mungkin terjadi

Sama seperti obat-obat yang lain, obat ini juga dapat menimbulkan efek samping, sekalipun tidak semua orang akan mengalami efek samping tersebut.

Penilaian efek samping berdasarkan frekuensi timbulnya efek samping tersebut.

Efek samping yang tercantum di bawah ini dapat terjadi karena penggunaan peritoneal dialisis secara umum:

Sangat sering (dapat terjadi lebih dari 1 diantara 10 orang pengguna)

- Peradangan peritoneum dengan tanda kekeruhan larutan/cairan dialisat, nyeri abdominal, demam, perasaan tidak enak, atau dalam kasus yang sangat jarang adalah keracunan darah. Tunjukkan kantong berisi larutan/cairan dialisat kepada dokter Anda.
- Peradangan kulit pada lokasi keluarnya kateter atau di sepanjang jalur kateter, yang dikenali dengan adanya kemerahan, bengkak, nyeri, luka terbuka atau krista.
- Hernia di daerah dinding abdominal.

Silahkan untuk segera kontak dokter Anda jika Anda menemukan salah satu dari efek samping di atas.

Efek samping lain yang mungkin terjadi adalah:

Sering (Dapat terjadi lebih dari 1 diantara 100 orang pengguna hingga kurang dari 1 diantara 10 orang pengguna)

- Timbulnya masalah dengan *inflow* atau *outflow* dari larutan/cairan dialisat.
- Sensasi seperti *stretching* (tertarik) atau penuh di abdomen.
- Nyeri bahu/pundak.

Jarang (Dapat terjadi lebih dari 1 diantara 10.000 orang pengguna hingga kurang dari 1 diantara 1.000 orang pengguna)

- Diare
- Konstipasi

Tidak diketahui (frekuensi tidak dapat diperkirakan berdasarkan data yang ada)

- Kesulitan bernafas oleh karena adanya kenaikan posisi diafragma.

Efek samping di bawah ini adalah yang mungkin terjadi dengan penggunaan CAPD/ DPCA 17:

Sangat sering (dapat terjadi lebih dari 1 diantara 10 orang pengguna)

- Defisiensi kalium

Sering (Dapat terjadi lebih dari 1 diantara 100 orang pengguna hingga kurang dari 1 diantara 10 orang pengguna)

- Kadar glukosa darah tinggi
- Kadar lemak darah tinggi
- Kenaikan berat badan

Jarang (Dapat terjadi lebih dari 1 diantara 10.000 orang pengguna hingga kurang dari 1 diantara 1.000 orang pengguna)

- Defisiensi Kalsium
- Kadar cairan di dalam darah sangat rendah, dapat dikenali dengan adanya penurunan berat badan yang cepat.
- Pusing
- Tekanan darah rendah
- Denyut nadi cepat
- Kadar cairan di dalam tubuh tinggi, dapat dikenali dengan kenaikan berat badan yang cepat.
- Tekanan darah tinggi
- Kesulitan bernafas

Tidak diketahui (frekuensi tidak dapat diperkirakan berdasarkan data yang ada)

- Paratiroid overaktif dengan potensi gangguan metabolisme tulang.

Laporan Efek Samping:

Jika Anda mengalami efek samping di atas, komunikasikan dengan dokter, farmasis atau perawat Anda. Hal itu berlaku juga untuk semua kemungkinan efek samping yang tidak tertulis di dalam daftar di atas. Pelaporan efek samping yang Anda lakukan membantu memberikan informasi mengenai profil keamanan dari obat ini.

5. Bagaimana cara penyimpanan CAPD/DPCA 17

Simpan obat ini jauh dari penglihatan dan jangkauan anak-anak.

Jangan gunakan obat ini setelah melebihi tanggal kadaluarsa. Tanggal kadaluarsa mengacu kepada hari terakhir dari bulan berjalan.

Simpan di bawah suhu 30˚C.

Jangan dimasukkan ke dalam kulkas maupun *freezer*.

Larutan/cairan harus segera digunakan setelah dibuka.

6. Isi dari kemasan dan informasi lain

Apa kandungan dari CAPD/DPCA 17

Zat aktif di dalam 1 L larutan / cairan adalah:

Kalsium klorida dihidrat	0,1838 g
Sodium klorida	5,786 g
Larutan Sodium-(S)-laktat [3,925 g Sodium-(S)-laktat]	7,85 g
Magnesium hidroklorida heksahidrat	0,1017 g
Glukosa monohidrrat (15,0 g glukosa) Fruktosa sampai dengan 0,75 g	16,5 g

Kuantitas tersebut di atas setara dengan:

1,25 mmol/L kalsium, 134 mmol/L sodium, 0,5 mmol/L magnesium, 102,5 mmol/L klorida, 35 mmol/L laktat dan 83,2 mmol/L glukosa.

Zat tambahan lain dari CAPD/DPCA 17 adalah WFI (*water for injections*), asam hidroklorat, dan sodium hidroksida.

Bagaimana tampilan dari CAPD/DPCA 17 dan kandungan di dalam kantongnya:

Larutan/cairan bening/jernih dan tidak berwarna sampai sedikit kekuningan.

Secara teoritis osmolalitas larutan/cairan adalah 356 mOsm/L, pH sekitar 5,5.

CAPD/DPCA 17 tersedia dalam bentuk sistem aplikasi dan ukuran sebagai berikut:

stay•safe link
Kantong 6x2000 mL

Reg. No. 000000000000000

Pemegang Lisensi:
PT. Ethica Industri Farmasi, Jakarta, Indonesia

Diimpor dan Didistribusikan oleh:
PT. Fresenius Medical Care Indonesia,
Tempo Scan Tower, 20th FL, JL. HR. Rasuna Said Kav 3-4, Jakarta, Indonesia.

Diproduksi oleh:
Fresenius Medical Care Production Sdn. Bhd.
Lot 34618, PT 29466
Techpark@Enstek
71760 Bandar Enstek
Negeri Sembilan
Malaysia

HARUS DENGAN RESEP DOKTER

This leaflet was last revised in February (Month) 2020 (Year).